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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,038	09/17/2003	Penelope Mavromara	03495-0194-01	3906

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EXAMINER

KETTER, JAMES S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,038

Applicant(s)

MAVROMARA ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-22 and 33-42 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-22, 33, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/18/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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Applicant's election without traverse of Group I, claims 10-22, 33, 40 and 41, in the reply filed on 30 June 2005 is acknowledged.

Claims 34-39 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 30 June 2005.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-14 and 16-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant invention is drawn to polypeptides including an "allelic variant" or "homolog" of core+1 polypeptide, or in the case of claims 15 and 16, mutants. However, the potential genus of such variants or homologs is vast, encompassing any sequence variation or chemical modification of the polypeptide backbone or side chains of the component amino acids. No information regarding the effects of such structural variation or modification on the function of the polypeptide is set forth either in the specification or in the prior art. The relationship of structure of polypeptides to their function is and was insufficiently developed in the art to permit

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a priori knowledge of at least a representative sample of such variant structures that would retain the disclosed function. As such, one of skill in the art would not have recognized that Applicants were in possession of the full scope of the claimed invention. With respect to claims 17-22, each of these claims is drawn to antibodies that bind to one of the polypeptide embodiments discussed above. However, where the description of the polypeptides is inadequate, i.e., incomplete, so, too, must be the description of the antibodies specific for them.

Claims 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors have been considered in the rejection:

The amount of direction or guidance presented in the specification, and the presence or absence of working examples. The specification sets forth very limited guidance, giving only brief, general guidelines for determining the dose of the immunogenic composition. The prior art is referred to, for general guidance. No working examples of a vaccine or other immunogenic composition are set forth.

The state of the prior art, and the predictability or unpredictability of the art. Hunziker et al. (U, newly cited) is a post-filing reference which teaches, e.g., at page 480, left-hand column, first full paragraph, that the art of peptide-based vaccines in HCV was unpredictable, with particular problems cited. Generally from Hunziker et al. it is learned that such a vaccine for HCV was unknown and presumed still to be problematic at the time of filing.

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Conclusion. Were the skilled practitioner in the art to have attempted to make and use a vaccine or other immunogenic composition according to the instant claims, said practitioner would have turned first to the specification for guidance. However, the specification gives only generalities, and no evidence or teaching of a working embodiment, appearing to rely mostly on the prior art for the requisite teachings. However, as set forth above, the prior art did not know of a working peptide-based vaccine for HCV, citing instead only problems to be overcome before success could be achieved. Finally, the skilled practitioner would have been forced to rely upon empirical experimentation to develop the claimed immunogenic composition. However, where the specification does not teach any working examples, and where the prior, and even the post-filing art cannot present guidance, but instead only recites the obstacles and modes of unpredictability, such experimentation to make and use the claimed invention would have been deemed undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant invention is drawn to polypeptides including an "allelic variant" or "homolog" of core+1 polypeptide, or in the case of claims 15 and 16, mutants. However, it is not clear what types or degrees of variation are intended to be encompassed within the scope of

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the instant claims. For example, would a polypeptide wherein all of the core+1 sequence had been removed and replaced with a completely different polypeptide be regarded as an allelic variant, homolog or mutant within the scope of the claims? And if not, what degree of substitution would be the maximum still encompassed? Since these are not clear, the metes and bounds of the instant claims are indefinite.

With regard to claims 17-22, to the extent that the recited polypeptides are of unclear scope, the metes and bounds of the claimed antibodies must necessarily be indefinite as well.

Claims 13 and 15 depend from cancelled claims, and thus claims 14-16 and 20-22 which depend from 13 or 15 ultimately share this dependence from cancelled claims. As such, the scope of the instant claims cannot be determined.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jsk
September 1, 2005



JAMES KETTER
PRIMARY EXAMINER